UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

PATRICK A. De LUCA, individually and on behalf of all others similarly situated,

Plaintiff,

-against-

SANOFI-AVENTIS U.S. LLC;
SANOFI US SERVICES INC.;
CHATTEM, INC.;
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.;
GLAXOSMITHKLINE, LLC; and,
PFIZER, INC.

Defendants.

CLASS ACTION COMPLAINT

Jury Trial Demanded

INTRODUCTION

1. Zantac is the brand name for Ranitidine. Zantac and Ranitidine are used to treat certain stomach and throat problems such as erosive esophagitis, gastroesophageal reflux disease ("GERD"), and Zollinger-Ellison syndrome. Zantac is also used to treat ulcers of the stomach and intestines and prevent them from coming back after they have healed.

2. Zantac works by decreasing the amount of acid created by the stomach. Zantac relieves symptoms such as persistent coughs, stomach pain, heartburn, and

difficulty swallowing. Zantac and Ranitidine belong to a class of drugs known as H2 receptor blockers.

3. N-Nitrosodimethylamine ("NDMA") is a potent carcinogen. It used to be a chemical biproduct of making rocket fuel in the early 1900s but, today, its only use is to induce tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no business being in a human body.

4. Zantac leads to the production of staggering amounts of NDMA when it is digested by the human body. The U.S. Food and Drug Administration's ("FDA") allowable daily limit of NDMA is 92 ng (nanograms) and yet, in a single dose of Zantac, researchers are discovering over 3 million ng.

5. These recent revelations by independent researchers have caused widespread recalls of Zantac both domestically and internationally, and the FDA is actively investigating the issue, with its preliminary results showing "unacceptable" levels of NDMA.

6. Plaintiff is an individual who purchased the over-the-counter version of the drug Zantac in New York.

7. Had Plaintiff and class members known that taking Zantac would expose them to high levels of the carcinogen NDMA, they would not have purchased the drug.

8. Plaintiff brings this action on behalf of himself and on behalf of a class consisting of individuals who purchased Zantac in the State of New York.

PARTIES

9. Plaintiff Patrick A. De Luca is an adult individual and a citizen of the State of New York, who resides at 156 Figueroa Avenue, Staten Island, New York 10312.

10. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi.

11. Defendant Sanofi US Services Inc. is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi.

12. Defendant Chattem, Inc. is a Tennessee corporation with a principal place of business at 1715 West 38th Street Chattanooga, Tennessee 37409, and is a wholly owned subsidiary of the French company Sanofi.

13. Defendants Sanofi-Aventis U.S. LLC; Sanofi US Services Inc.; and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants") controlled the U.S. rights to over-the-counter Zantac from about January 2017 to the present, and manufactured and distributed the drug in the United States during that period.

14. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") is a Delaware corporation with a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877, and is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned the U.S. rights to over-the-counter Zantac from about October 2006 to January 2017, and manufactured and distributed the drug in the United States during that period.

15. Defendant GlaxoSmithKline, LLC ("GSK") is a Delaware corporation with its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania, 19112 and Five Moore Drive, Research Triangle, North Carolina, 27709. GSK was the original innovator of the Zantac drug and controlled the NDA for prescription Zantac between 1983 and 2009. By controlling the Zantac NDA it also directly controlled the labeling for all Zantac products through 2009. GSK's negligence and misconduct related to Zantac as an innovator directly led to the failure to warn for other OTC versions of Zantac.

16. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer was the original NDA holder for OTC Zantac, and controlled the NDA between August 2004 and December 2006.

JURISDICTION AND VENUE

17. Jurisdiction exists under 28 U.S.C. §1332(d), which provides original jurisdiction over any civil action in which the matter in controversy exceeds the sum or value of $5 million, exclusive of interests and costs, and is a class action in which any member of a class of plaintiffs is a citizen of a state different from any defendant.

18. The Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in this District. Defendants' unlawful conduct has injured persons residing in, located in, or doing business throughout this District.

19. Venue is proper in this judicial district pursuant to 28 U.S.C. §1391(b) and (c) each Defendant transacts business in, is found in, and/or has agents in this district, and because a substantial part of the events giving rise to this action occurred within this district.

BACKGROUND

20. Zantac was developed by GlaxoSmithKline ("GSK") and approved for prescription use by the FDA in 1983. The drug belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

21. Due in large part to GSK's marketing strategy, Zantac was a wildly successful drug, reaching $1 billion in total sales in December 1986. As one 1996 article put it, Zantac became "the best-selling drug in history as a result of a shrewd, multifaceted marketing strategy that . . . enabled the product to dominate the acid/peptic marketplace." Significantly, the marketing strategy that led to Zantac's success emphasized the purported safety of the drug.

22. Zantac became available without a prescription in 1996, and generic versions of the drug (ranitidine) became available the following year. Although sales of brand-name Zantac declined as a result of generic and alternative products, Zantac sales have remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million—a 3.1% increase from the previous year.

23. On September 13, 2019, in response to a citizen's petition filed by Valisure, Inc. (discussed below), U.S. and European regulators stated that they are reviewing the safety of ranitidine.

24. On September 18, 2019, Novartis AG's Sandoz Unit, which makes generic drugs, stated that it was halting the distribution of its versions of Zantac in all markets, while Canada requested drug makers selling ranitidine to stop distribution.

25. On September 28, 2019, CVS Health Corp. stated that it would stop selling Zantac and its own generic ranitidine products out of concern that it might contain a carcinogen.

26. CVS has been followed by Walmart, Inc., Walgreens Boot Alliance, and Rite Aid Corp. to also remove Zantac and ranitidine products.

27. On October 2, 2019, the FDA stated that it was ordering all manufacturers of Zantac and ranitidine products to conduct testing for NDMA because preliminary results indicated unacceptable levels.

28. At no time did any Defendant attempt to include a warning about NDMA or any cancer, nor did the FDA ever reject such a warning. Defendants had the ability to unilaterally add an NDMA and/or cancer warning to the Zantac label (for both prescription and OTC) without prior FDA approval pursuant to the Changes Being Effected regulation.

29. NDMA is a semi-volatile organic chemical that forms in both industrial and natural processes. It is a member of N-nitrosamines, a family of potent carcinogens. The dangers that NDMA poses to human health have long been recognized. A news article published in 1979 noted that "NDMA has caused cancer in nearly every laboratory animal tested so far." NDMA is no longer produced or commercially used in the United States, except for research, such as a tumor initiator in certain animal bioassays. In other words, it is only a poison.

30. Both the Environmental Protection Agency ("EPA") and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen. The World Health Organization ("WHO") has stated that scientific testing indicates that NDMA consumption is positively associated with either gastric or colorectal cancer and suggests that humans may be especially sensitive to the carcinogenicity of NDMA.

31. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

32. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—valsartan, losartan, and irbesartan—because the medications contained nitrosamine impurities that do not meet the FDA's safety standards. The FDA has established a permissible daily intake limit for the probable human carcinogen, NDMA, of 96 ng (nanogram). However, the highest level of NDMA detected by the FDA in any of the Valsartan tablets was 20.19 μg (or 20,190 ng) per tablet. In the case of Valsartan, the NDMA was an impurity caused by a manufacturing defect, and thus NDMA was present in only some products containing valsartan. Zantac poses a greater safety risk than any of the recently recalled valsartan tablets. Not only is NDMA a

byproduct of the ranitidine molecule, itself, but the levels observed in recent testing show NDMA levels in excess of 3,000,000 ng.

33. In mouse studies examining the carcinogenicity of NDMA through oral administration, animals exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, similar cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, similar cancers were observed in the liver, pancreas, and stomach. In comparable Guinea-pig studies, similar cancers were observed in the liver and lung. In comparable rabbit studies, similar cancers were observed in the liver and lung.

34. In other long-term animal studies in mice and rats utilizing different routes of exposures—inhalation, subcutaneous injection, and intraperitoneal (abdomen injection)—cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

35. Alarmingly, Zantac is in the FDA's category B for birth defects, meaning it is considered safe to take during pregnancy. However, in animal experiments, for those animals exposed to NDMA during pregnancy, the offspring had elevated rates of cancer in the liver and kidneys.

36. In addition, NDMA breaks down into various derivative molecules that, themselves, are associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestine (including colon).

37. Research shows that lower levels of NDMA, i.e., 40 ng, are fully metabolized in the liver, but high does enter the body's general circulation.

38. Numerous in vitro studies confirm that NDMA is a mutagen—causing mutations in human and animal cells.

39. Overall the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice, rats, Syrian golden, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, fish, newts, and frogs.

40. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."

41. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. While these studies consistently show increased risks of various cancers, the exposure levels considered in these studies are a very small fraction—as little as 1 millionth—the exposures noted in a single Zantac capsule, i.e., 0.191 ng/day (dietary) v. 304,500 ng/day (Zantac).

42. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 ng/day.

43. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng/day.

44. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at .179 ng/day.

45. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "N-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.

46. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, pharynx, prostate, and brain cancer.

47. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.

48. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.

49. The high levels of NDMA produced by Zantac are not caused by a manufacturing defect but are inherent to the molecular structure of ranitidine, the active ingredient in Zantac.

50. The ranitidine molecule contains both a nitrite and a dimethylamine ('DMA') group which are well known to combine to form NDMA. Thus, ranitidine produces NDMA by "react[ing] with itself", which means that every dosage and form of ranitidine, including Zantac, exposes users to NDMA.

51. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the American water supply. Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.

52. The high instability of the ranitidine molecule was further elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed, as shown in Figure 2 above. These studies underscore the instability of the NDMA group on

the ranitidine molecule and its ability to form NDMA in the environment of water treatment plants which supply many American cities with water.

53. These studies did not appreciate the full extent of NDMA formation risk from ranitidine; specifically, the added danger of this drug having not only a labile DMA group but also a readily available nitroso source in its nitrite group on the opposite terminus of the molecule. Recent testing of NDMA levels in ranitidine batches are so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

54. Tobacco smoke also contains NDMA. One filtered cigarette contains between 5 – 43 ng of NDMA

55. Valisure, LLC is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO")—an accreditation recognizing the laboratories technical competence for regulatory. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

56. As part of its testing of Zantac, and other ranitidine products, Valisure discovered exceedingly high levels of NDMA in every lot tested. Valisure's ISO

17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.13 The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet.

57. Valisure's testing shows, on average, 2,692,291 ng of NDMA in a 150 mg Zantac tablet. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at 28,000 times the legal limit. In terms of smoking, a person would need to smoke at least 6,200 cigarettes to achieve the same levels of NDMA found in one 150 mg dose of Zantac.

58. Valisure, however, was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

59. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF" 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF" 50 mM potassium

chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs.

60. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, etc.

61. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present.

62. Under biologically relevant conditions, when nitrites are present, staggeringly high levels of NDMA are found in one dose of 150 mg Zantac, ranging between 245 and 3,100 times above the FDA-allowable limit. In terms of smoking, one would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 ng level (over 7,000 for the 50 µg level).

63. Antacid drugs are known to increase stomach pH and thereby increase the growth of nitrite-reducing bacteria which further elevate levels of nitrite. This fact is well known and even present in the warning labels of antacids like Prevacid (lansoprazole) and was specifically studied with ranitidine in the original approval

of the drug. Thus, higher levels of nitrites in patients regularly taking Zantac would be expected.

64. In fact, NDMA formation in the stomach has been a concern for many years. Specifically, ranitidine has been implicated as a cause of NDMA formation by multiple research groups, including those at Stanford University.

65. Existing research shows that ranitidine interacts with nitrites and acids in the chemical environment of the human stomach to form NDMA. In vitro tests demonstrate that when ranitidine undergoes "nitrosation" (the process of a compound being converted into nitroso derivatives) by interacting with gastric fluids in the human stomach, the by-product created is dimethylamine ("DMA")—an amine present in ranitidine itself. When DMA is released, it can be nitrosated even further to form NDMA, a secondary N-nitrosamine.

66. Moreover, in addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH") which can occur in other tissues and organs separate from the stomach.

67. Liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the

kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."

68. These results indicate that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

69. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the liver, prostate, stomach, bladder, brain, colon, and prostate. This offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs, including the bladder.

70. In addition to the aforementioned in vitro studies that suggest a strong connection between ranitidine and NDMA formation, in vivo clinical studies in living animals add further weight to concern over this action and overall potential carcinogenicity. A study published in the journal Carcinogenesis in 1983 titled "Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite" specifically suspected the carcinogenic nature of ranitidine in combination with nitrite. The authors of this study concluded: "Our experimental findings have shown

that simultaneous oral administration in rats of high doses of ranitidine and NaNO2 [nitrite] can produce DNA fragmentation either in liver or in gastric mucosa."

71. The human data, although limited at this point, is even more concerning. A study completed and published in 2016 by Stanford University observed that healthy individuals, both male and female, who ingested Zantac 150 mg tablets produced roughly 400 times elevated amounts of NDMA in their urine (over 47,000 ng) in the proceeding 24 hours after ingestion.

72. Likely due to the perceived high safety profile of ranitidine, very few epidemiological studies have been conducted on this drug.

73. A 2004 study published by the National Cancer Institute investigated 414 cases of peptic ulcer disease reported in 1986 and followed the individual cases for 14 years.18 One of the variables investigated by the authors was the patients' consumption of a prescription antacid, either Tagamet (cimetidine) or Zantac (ranitidine). The authors concluded that "[r]ecent use of ulcer treatment medication (Tagamet and Zantac) was also related to the risk of bladder cancer, and this association was independent of the elevated risk observed with gastric ulcers."

74. Specifically, the authors note that "N-Nitrosamines are known carcinogens, and nitrate ingestion has been related to bladder cancer risk." NDMA is among the most common of the N- Nitrosamines.

75. A 1982 clinical study in rats compared ranitidine and cimetidine exposure in combination with nitrite. When investigating DNA fragmentation in the rats' livers, no effect was observed for cimetidine administered with nitrite, but ranitidine administered with nitrite resulted in a significant DNA fragmentation.

76. Investigators at Memorial Sloan Kettering Cancer Center are actively studying ranitidine to evaluate the extent of the public health implications of these findings. Regarding ranitidine, one of the investigators commented: "A potential link between NDMA and ranitidine is concerning, particularly considering the widespread use of this medication. Given the known carcinogenic potential of NDMA, this finding may have significant public health implications[.]"

77. During the time that Defendants manufactured and sold Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA. Defendants failed to disclose this risk to consumers on the drug's label—or through any other means—and Defendants failed to report these risks to the FDA.

78. Going back as far as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested. This was known or should have been known by Defendants.

79. Defendants concealed the Zantac–NDMA link from consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such

as those who submit citizen petitions) to bring new information about an approved drug like Zantac to the agency's attention.

80. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

81. The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

82. "The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product." 21 C.F.R. § 314.81(b)(2)(v).

83. Defendants ignored these regulations and, disregarding the scientific evidence available to them, did not report to the FDA significant new information affecting the safety or labeling of Zantac.

84. Defendants never provided the relevant studies to the FDA, nor did they present to the FDA with a proposed disclosure noting the link between ranitidine and NDMA.

85. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography. Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiffs believe this was intentional—a gambit by the manufacturer to avoid detecting a carcinogen in their product.

86. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds (discussed previously), GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds. This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to fail. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N- nitrosamines. Furthermore, in addition to this approach being less accurate, GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."

Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed.

87. Again, this spurious test was intentional and designed to mask any potential cancer risk.

88. There are multiple alternatives to Zantac that do not pose the same risk, such as Cimetidine (Tagamet), Famotidine (Pepcid), Omeprazole (Prilosec), Esomeprazole (Nexium), and Lansoprazole (Prevacid).

89. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants were fully aware of the safety risks of Zantac, particularly the carcinogenic potential of Zantac as it transforms into NDMA within the chemical environment of the human body. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to mislead consumers.

90. This was not done by accident or through some justifiable negligence. Rather, Defendants knew that they could turn a profit by convincing consumers that Zantac was harmless to humans, and that full disclosure of the true risks of Zantac would limit the amount of money Defendants would make selling Zantac. Defendants' objective was accomplished not only through their misleading labels, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout this

pleading. Plaintiff and the Class were denied the right to make informed decisions about whether to purchase and use Zantac, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

91. Within the time period of any applicable statute of limitations, Plaintiff could not have discovered through the exercise of reasonable diligence that exposure to Zantac is injurious to human health.

92. Plaintiff did not discover and did not know of facts that would cause a reasonable person to suspect the risk associated with the use of Zantac.

93. The expiration of any applicable statute of limitations has been equitably tolled by reason of Defendants' misrepresentations and concealment. Through affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff the true risks associated with use of Zantac.

94. As a result of Defendants' actions, Plaintiff and the Class could not reasonably have known or learned through reasonable diligence that Plaintiff and the Class had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

95. Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of Zantac. Defendants had a duty to disclose the true character, quality and nature of Zantac because this was non-public information over which Defendants continue to have control.

Defendants knew that this information was not available to Plaintiff and the Class, yet Defendants failed to disclose the information to the public.

96. Defendants had the ability to and did spend enormous amounts of money in furtherance of marketing and promoting a profitable product, notwithstanding the known or reasonably knowable risks. Plaintiff the Class could not have afforded to, and could not have possibly conducted, studies to determine the nature, extent, and identity of related health risks and were forced to rely on Defendants' representations.

CLASS ACTION ALLEGATIONS

97. Plaintiffs bring this action under Federal Rule of Civil Procedure 23(a) and (b)(3), on behalf of themselves and all other similarly situated.

98. Subject to confirmation, clarification, or modification based on discovery to be conducted in this action, the Class that Plaintiff seeks to represent is defined as follows: All persons who purchased over-the-counter Zantac in the State of New York for personal, family, or household use.

99. Excluded from the Class are each Defendant and any entity in which a Defendant has a controlling interest, as well as any Defendant's legal representatives, officers, directors, assignees, and successors.

100. Members of the Class are so numerous that joinder of all members is impracticable. Over-the-counter Zantac was one of the best-selling antacid

medications in the United States. Hundreds of thousands—if not millions—of persons purchased the drug.

101. Class members are readily identifiable from information and records in the possession of Defendants and third-party pharmacies such as CVS, Walgreens, Walmart, and Rite Aid.

102. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all Class members were damaged by the same wrongful conduct of Defendants. As a result of Defendants' failure to disclose that Zantac exposed users to unsafe levels of the carcinogen NDMA, Plaintiffs and Class members were misled into purchasing Zantac—a drug they otherwise would not have purchased. There are numerous Zantac substitutes; in addition to other H2 blockers such as Pepcid-AC and Tagamet-HB, there are also proton pump inhibitors—for example, Dexilant, Nexium, Prevacid, Protonix, AcipHex, and Prilosec—which "block the enzyme in the stomach wall that makes acid."

103. Plaintiffs will fairly and adequately protect and represent the interests of the Class.

104. The interests of Plaintiffs are coincident with, and not antagonistic to, those of the other Class members.

105. Plaintiffs' counsel are experienced in the prosecution of class-action litigation and have particular experience with class-action litigation involving pharmaceutical products.

106. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful actions.

107. Questions of law and fact common to the Class include, but are not limited to:

a. Whether the Zantac sold by Defendants exposed Plaintiffs and Class members to unsafe levels of the carcinogen NDMA;

b. Whether Defendants knew or had reason to know that Zantac exposes users to unsafe quantities of NDMA;

c. Whether Defendants acted to conceal from consumers that Zantac exposes users to unsafe quantities of NDMA;

d. Whether Defendants' conduct was knowing or willful;

e. Whether Defendants notified the FDA that Zantac exposes users to unsafe quantities of NDMA;

f. Whether Defendants attempted to gain approval from the FDA to change Zantac's label to add a warning that the drug exposes users to unsafe quantities of NDMA;

g. Whether Defendants acted to conceal from the FDA the link between Zantac and NDMA;

h. Whether Defendants' failure to disclose on Zantac's label (or elsewhere) that the drug produces high levels of the carcinogen NDMA was unfair, deceptive, fraudulent, or unconscionable;

i. Whether Defendants are liable to Plaintiffs and Class members for damages under state consumer-protection statutes;

j. When Defendants manufactured and sold Zantac in the United States;

k. Whether an injunction should be issued requiring defendants to disclose on Zantac labels that the drug exposes users to unsafe levels of NDMA; and

l. Whether Plaintiffs and Class members are entitled to attorneys' fees, prejudgment interest, and costs, and if so, in what amount.

108. Plaintiffs and Class members have all suffered harm and damages as a result of Defendants' unlawful and wrongful conduct.

109. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Such treatment will

permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender.

110. The benefits of proceeding through the class mechanism—including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually—substantially outweigh potential difficulties in management of this class action. Absent a class action, most members of the Class would find the cost of litigating their claims to be prohibitive and will have no effective remedy at law.

111. The class treatment of common questions of law and fact also is superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to Plaintiffs and the Class and require court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

112. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

COUNT I
Breach of Express Warranty

113. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs.

114. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

115. Plaintiff, and each member of the Class, formed a contract with Defendants at the time Plaintiff and the other Class members purchased the defective Zantac. The terms of the contract include the promises and affirmations of fact made by Defendants on Zantac's packaging and through marketing and advertising, including that the product would contain only what was stated on the label, and not harmful impurities such as NDMA. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and Defendants.

116. Plaintiff relied on the express warranty that his Zantac was safe and would not contain unsafe levels of NDMA. This express warranty further formed the basis of the bargain, and is part of the standardized contract between Plaintiff and the members of the Class and Defendants.

117. Defendants purport, through their advertising, labeling, marketing and packaging, to create an express warranty that the medication would contain only the ingredients stated on the label, and not harmful impurities such as NDMA.

118. Plaintiff and the Class performed all conditions precedent to Defendants' liability under this contract when they purchased the defective medication.

119. Defendants breached express warranties about the defective Zantac and its qualities because Defendants' statements about the defective Zantac were false and the defective Zantac does not conform to Defendants' affirmations and promises described above.

120. Plaintiff and each of the members of the Class would not have purchased the defective Zantac had they known the true nature of the defective Zantac's composition, specifically that Zantac contained elevated levels of NDMA.

121. As a result of Defendants' breaches of express warranty, Plaintiff and each of the members of the Class have been damaged in the amount of the purchase price of Zantac and any consequential damages resulting from the purchases.

COUNT II
Breach of The Implied Warranty Of Merchantability

122. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

123. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

124. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that Zantac:

a. would not contain elevated levels of NDMA; and,

b. is generally recognized as safe for human consumption.

125. Defendants breached these implied warranties because the Zantac manufactured, distributed, and sold by Defendants contained elevated levels of carcinogenic and liver toxic NDMA, and as such is not generally recognized as safe for human consumption. As a result, Plaintiff and Class members did not receive the goods as impliedly warranted by Defendants to be merchantable.

126. Plaintiff and Class members purchased Zantac in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

127. The Zantac was not altered by Plaintiff or Class members.

128. The Zantac was defective when it left the exclusive control of Defendants.

129. Defendants knew that the Zantac would be purchased and used without additional testing by Plaintiff and Class members.

130. The defective Zantac was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class members did not receive the goods as warranted.

131. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class members have been injured. Plaintiff and Class members would not have purchased Zantac on the same terms if they knew that Zantac contained harmful levels of NDMA, and is not generally recognized as safe for human consumption. Moreover, Zantac does not have the characteristics, ingredients, uses, or benefits promised by Defendants.

COUNT III
Violation Of New York General Business Law § 349

132. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

133. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

134. New York's General Business Law §349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

135. In its sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of New York's General Business Law §349.

136. Plaintiff and members of the Class are consumers who purchased products from Defendants for their personal use.

137. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that Zantac:

a. would not contain dangerously high levels of NDMA; and,

b. is generally recognized as safe for human consumption.

138. The foregoing deceptive acts and practices were directed at consumers.

139. The foregoing deceptive acts and practices were misleading in a material way because they fundamentally misrepresented the characteristics and quality of Zantac to induce consumers to purchase the same.

140. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

141. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of the Class have sustained from having paid for and used Defendants' products.

142. As a result of Defendants' violations, Plaintiff and members of the Class have suffered damages. Plaintiff and Class members would not have purchased Zantac on the same terms if they knew that Zantac contained harmful levels of NDMA, and is not generally recognized as safe for human consumption.

Moreover, Zantac does not have the characteristics, ingredients, uses, or benefits promised by Defendants.

143. On behalf of himself and other members of the Class, Plaintiff seeks to recover his actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Violation Of New York General Business Law § 350

144. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

145. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

146. New York's General Business Law §350 prohibits false advertising in the conduct of any business, trade, or commerce.

147. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

148. Based on the foregoing, Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of §350 of New York's General Business Law.

149. Defendants' false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

150. Defendants' false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

151. Defendants' false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

152. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, Plaintiff and the Class have suffered and continue to suffer economic injury.

153. As a result of Defendants' violations, Plaintiff and members of the Class have suffered damages. Plaintiff and Class members would not have purchased Zantac on the same terms if they knew that Zantac contained harmful levels of NDMA, and is not generally recognized as safe for human consumption. Moreover, Zantac does not have the characteristics, ingredients, uses, or benefits promised by Defendants.

154. On behalf of himself and other members of the Class, Plaintiff seeks to recover his actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
Unjust Enrichment

155. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

156. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

157. Plaintiff and the Class conferred a benefit on Defendants in the form of monies paid to purchase Defendants' defective Zantac.

158. Defendants' induced payment through false, misleading, and deceptive statements regarding the nature and safety of Zantac, relied upon by the Plaintiff and the Class members.

159. Defendants sought, voluntarily accepted, and retained this benefit.

160. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for human use, it would be unjust and inequitable for the Defendants to retain it without paying the value thereof.

161. Defendants should therefore be ordered to disgorge all moneys paid by Plaintiff and Class members in connection with the purchase of defective Zantac.

COUNT VI
Fraudulent Concealment

162. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

163. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendants.

164. Defendants had a duty to disclose material facts to Plaintiff and the Class given their relationship as contracting parties and intended users of Zantac. Defendants also had a duty to disclose material facts to Plaintiff and the Class, namely that they were in fact manufacturing, distributing, and selling harmful Zantac unfit for human consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

165. Defendants possessed knowledge of these material facts. In 2003, it was "proposed that elevated levels of NDMA in drinking water…may be associated with the drug ranitidine." Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable." During that time, Plaintiff and/or Class members were using Zantac without knowing it contained dangerous levels of NDMA.

166. Defendants failed to discharge their duty to disclose these materials facts.

167. In so failing to disclose these material facts to Plaintiff and the Class, Defendants intended to hide from Plaintiff and the Class that they were purchasing

and consuming Zantac with harmful defects that was unfit for human use, and thus acted with scienter and/or an intent to defraud.

168. Plaintiff and the Class reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the defective Zantac manufactured, distributed, and sold by Defendants had they known it contained unsafe levels of NDMA.

169. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiff and the Class suffered damages in the amount of monies paid for the defective Zantac.

170. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VII
Fraud

171. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

172. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

173. As discussed above, Defendants provided Plaintiff and Class members with materially false or misleading information about the Zantac manufactured, distributed, and sold by Defendants. Specifically, Defendants have marketed Zantac as safe for human consumption. As indicated above, however, these representations

are false and misleading as Defendants' Zantac medications contained elevated levels of NDMA.

174. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class members to purchase defective Zantac.

175. Defendants knew that Zantac was contaminated with this harmful impurity, but continued to manufacture it nonetheless. In 2003, it was "proposed that elevated levels of NDMA in drinking water … may be associated with the drug ranitidine." Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable." During that time, Plaintiff and/or Class members were using the medication without knowing it contained dangerous levels of NDMA.

176. The fraudulent actions of Defendants caused damage to Plaintiff and Class members, who are entitled to damages and other legal and equitable relief as a result.

177. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VIII
Conversion

178. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

179. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendants.

180. Plaintiff and the Class have an ownership right to the monies paid for the defective Zantac manufactured, distributed, and sold by Defendants.

181. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the defective Zantac. Defendants have done so every time that Plaintiff and the Class bought Zantac over the counter.

182. As a direct and proximate cause of Defendants' conversion, Plaintiff and the Class suffered damages in the amount of the payments made for each time they bought Zantac over the counter.

REQUESTED RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the Class, seeks judgment against Defendants, jointly and severally, as follows:

A. A determination that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure Rule 23 and for an order certifying this case as a class action and appointing Plaintiffs as Class representative;

B. A declaration that Defendants' failure to disclose to consumers that Zantac produces unsafe levels of NDMA was unfair, deceptive, fraudulent, wrongful, and unlawful;

C. Restitution for all purchases of Zantac by Plaintiffs and the Class;

D. Disgorgement of the ill-gotten gains derived by Defendants from their misconduct;

E. Actual damages;

F. Statutory damages;

G. Punitive damages;

H. Treble damages;

I. Compensatory damages caused by Defendants' unfair or deceptive practices; along with exemplary damages to Plaintiffs and each Class member for each violation;

J. A permanent injunction requiring Defendants to either:

(i) cease selling Zantac, or

(ii) add a label to their Zantac packaging warning consumers of the high levels of NDMA they will be exposed to by taking the drug;

K. Pre-judgment and post-judgment interest at the maximum rate permitted by applicable law; and,

L. An order awarding Plaintiffs and the Class their attorney's fees, costs, and expenses incurred in connection with this action

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable.

Respectfully submitted,

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